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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,813	03/10/2004	Albert Crum	U015860-9	7474

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EXAMINER	
JUNG, UNSU	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,813	CRUM, ALBERT	
	Examiner	Art Unit	
	Unsu Jung	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-64* is/are pending in the application.

4a) Of the above claim(s) *21-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment to add new claims 63 and 64 and amend claims 45-62 in the reply filed on July 17, 2006 has been acknowledged and entered.

2. Claims 21-64 are pending and claims 45-64 are being considered for their merits.

Election/Restrictions

3. Applicant's election with traverse of Group II (claims 45-62) in the reply filed on July 17, 2006 is acknowledged. The traversal is on the ground(s) that claims define a single invention and that all of the claims should be examined in this application. Applicant further argues that the claims define methods of testing for lipid peroxide, pyroglutamic acid and glutathione and comparing the amounts of these compounds before, during and after treatment with an anti-oxidant. This is not found persuasive because each method of Groups I-IX and XI has a distinct step, which is not required by the others and the kit of Group X can be used in materially different process as discussed in Office Action filed on January 9, 2006. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because the search required for each Group is not required for the others, restriction for examination purposes as indicated is proper. Literature search

for each method and apparatus/product is distinct since the structural requirements of each invention are different. While searches would be expected to overlap, there is no reason to expect the searches to be coextensive.

The requirement is still deemed proper and is therefore made FINAL.

4. The Office Action dated June 29, 2005 (p8, paragraph 10) indicates that the Group II includes claims 45-65, which was a typographical error. The Group II should have included claims 33-62 as correctly indicated on p3.

Objections Withdrawn

5. Applicant's arguments, see p14, filed on July 17, 2006, with respect to the objection of the specification have been fully considered and are persuasive. The objection of the specification has been withdrawn.

6. Applicant's arguments, see pp14-15, filed on July 17, 2006, with respect to the objection of claims 51, 52, 55-58, and 60 have been fully considered and are persuasive. The objection of the specification has been withdrawn in light of the amended claims 51, 52, 55-58, and 60 in the reply filed on July 17, 2006.

Rejections Withdrawn

7. Applicant's arguments, see p15, filed on July 17, 2006, with respect to the rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the written

description requirement have been fully considered and are persuasive. The rejection of claims 51 and 56 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in light of the amended claims 51 and 56 in the reply filed on July 17, 2006.

8. Applicant's arguments, see p15, filed on July 17, 2006, with respect to the rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement have been fully considered and are persuasive. The rejection of claims 55 and 60 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn.

9. Applicant's arguments, see pp15-18, filed on July 17, 2006, with respect to the rejection under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The rejection of claims 45-62 under 35 U.S.C. 112, second paragraph has been withdrawn in light of Applicant's arguments and amended claims 45-52, 55-58, and 60-62 in the reply filed on July 17, 2006.

Specification

10. The disclosure is objected to because of the following informalities: the word "cystine" is misspelled and should be corrected to "cysteine" p54, paragraph [0163], line 2.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 50 and 55-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claims 50, 58, 63, and 64 contain the trademark/trade names IMMUNE FORMULATION 100™ and/or IMMUNE FORMULATION 200™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe anti-oxidant and, accordingly, the identification/description is indefinite.

Examiner notes that rejection of claims 50 and 58 under 35 U.S.C. 112, second paragraph for containing trademark/trade names IMMUNE FORMULATION 100™ and/or IMMUNE FORMULATION 200™ was not addressed by the Applicant in the reply filed on July 17, 2006. Therefore, the rejection of claims 50 and 58 under 35 U.S.C. 112, second paragraph have been maintained and further, claims 63 and 64, which contain trademark/trade name IMMUNE FORMULATION 200™, has been rejected under 35 U.S.C. 112, second paragraph.

14. In claim 55, the term "an anti-oxidant" in line 5 is vague and indefinite. It is unclear whether or not the term "an anti-oxidant" in line 5 is referring to "an anti-oxidant" in lines 1-2. For the purpose of examination, the term "an anti-oxidant" in line 5 has been interpreted as referring to "an anti-oxidant" in lines 1-2.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims 45, 53, 55, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillam (WO 01/89518 A1, Nov. 29, 2001) in view of Crawford (U.S. Patent No. 6,709,835, Filed Sept. 3, 1996) and Ajami (U.S. Patent No. 6,284,219, Filed June 30, 1998).

Gillam teaches a method of determining a dosage of anti-oxidant for an individual person, wherein the dosage is determined on the basis of an individual factor and a stress index (Abstract). Anti-oxidants are chemical molecules present in small amounts in the body that can accept an electron from oxygen radical, thus deactivating it, and preventing oxidative damage (p1, lines 18-20). The body produces its own anti-oxidants, the most important of which is glutathione (GSH, p1, lines 20-21). When the number of oxygen free radicals within the body increase beyond the amount of anti-oxidants in the body, the body is said to be under "oxidative stress" (p2, lines 9-10). These oxygen radicals rapidly react with fats, proteins and DNA, damaging their molecular structure, which can cause abnormal metabolic and cellular functions, disruptions in cell structure, leakage of essential enzymes involved in energy production and genetic damage that may lead to the development of chronic diseases, such as cancer (p2, lines 9-14). The levels of plasma GSH progressively decrease from 25 to 45 years of age to 50% of their original level (p6, lines 1-2). As a consequence, the

concentration of lipid peroxides, an index of oxidative damage to lipid, rises with increased age (p6, lines 2-4). It would be obvious to one of ordinary skill in the art to realize that the measurements of reduced levels of plasma GSH and increased lipid peroxide in aging individuals would require comparison between an aging group of individuals and a control group (normal standard). However, Gillam fails to teach a method measuring the amount of pyroglutamic acid levels in a sample of body fluid and that lipid peroxide levels were measured in a sample of body fluid.

Crawford teaches a method of measuring by products of free radical damage such as lipid peroxide and glutathione, which can be an indicator for oxidative stress, in serum or urine (column 2, lines 4-8 and lines 24-34). Crawford further teaches that glutathione is a well known cellular anti-oxidant and its function as powerful anti-oxidant is essential for cell-mediated immune functions (column 2, lines 13-20). Research in humans has indicated that deficient intakes of nutrient anti-oxidants are associated with higher risks of cancer, cardiovascular disease, arthritis, cataracts, etc. (column 1, lines 60-62). Also, a higher intake of nutrient anti-oxidants is associated with lower incidence of chronic degenerative diseases (column 1, lines 62-64). Encouraging studies indicate that intervention with anti-oxidant nutrient supplements may have therapeutic benefit in humans (column 1, lines 64-67).

Ajami teaches that the measurement of cytoprotective capacity and resistance to oxidative stress, as reflected in the glutathione cycle, is immediately applicable in cancer treatment to assess a given patient's ability to withstand a dose of chemotherapy (column 15, lines 58-52). Patients with AIDS, hepatitis, and long term

neurodegenerative disorders, such as Parkinson's and Alzheimer's disease might also benefit (column 15, lines 55-57). Ajami further teaches that the level of oxoproline (pyroglutamic acid, PGA), a natural substrate of oxoprolinase, is inversely proportional to the level of glutathione as oxoproline accumulates in toxic concentrations when glutathione synthesis is inhibited (column 16, lines 59-66) and oxoproline level is decreased during periods of high glutathione demand (column 16, line 59-column 17, line 5). Moreover, Ajami teaches a method of comparing between a metabolic index value obtained for the patient and the normative value for the control population. This method can be used as a tool in the selection of gradations in therapy and track a course of therapeutic treatment (column 16, lines 22-28).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Gillam with a method of measuring urine of serum level of lipid peroxide as taught by Crawford and a method of measuring PGA levels as taught by Ajami in order to assess oxidative stress levels, determine effective anti-oxidant therapy as glutathione, lipid peroxide, and PGA are indicators of oxidative stress in an individual, and track a course of therapeutic treatment.

With respect to claims 53 and 59, Ajami teaches a method, wherein the sample is urine (column 14, lines 5-8).

With respect to claim 54, Ajami teaches a method, wherein comparison of metabolic index value (lipid peroxide, PGA, and glutathione levels) of a patient to a normal individual is used to track a course of a therapeutic treatment (an indication of efficiency of utilization of anti-oxidant, column 16, lines 22-28).

18. Claims 46-49 and 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillam (WO 01/89518 A1, Nov. 29, 2001) in view of Crawford (U.S. Patent No. 6,709,835, Filed Sept. 3, 1996) and Ajami (U.S. Patent No. 6,284,219, Filed June 30, 1998) as applied to claims 45 and 55 above, and further in view of Khaled (U.S. Patent No. 5,977,073, Filed June 6, 1991).

Gillam in view of Crawford and Ajami teaches a method for measuring effectiveness of therapy with anti-oxidant in a subject receiving treatment with an anti-oxidant as discussed above. However, Gillam in view of Crawford and Ajami fails to teach a method, wherein the subject in need of treatment with an anti-oxidant also experiences a reduction in immune cell number and/or function.

Khaled teaches that an immune system can be compromised because of poor dietary habits or starvation, various environmental stresses that include physical, psychological, infection, trauma, ischemia, radiation, chemical exposure, cigarette, alcohol, or narcotic substance abuse, and the toxic effect of one or more therapeutic drugs (column 1, line 62-column 2, line 1). A paradigm of such stress is found in AIDS, which appears to involve several nutritional aberrations (column 2, lines 1-2). HIV is a T-cell lymphotropic retrovirus that severely infects T-helper cells, and causes severe malnutrition (column 2, lines 2-4). Such malnutrition increases the susceptibility of the patient to opportunistic diseases that form the basis of AIDS or AIDS related complex (column 2, lines 4-7). Among deficient nutrients in AIDS patients, or in HIV-infected patients, are anti-oxidants (column 2, lines 7-8). These immune disorders, which are

caused by a virus and/or bacterium, can be treated by using antiviral and/or antibacterial pharmacological agents together with a nutritional supplement, which both bolsters the immune competence of the patient and reduces the toxicity of the antiviral and/or antibacterial agent.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Gillam in view of Crawford and Ajami to include treating AIDS patients, or in HIV-infected patients, whose T-helper cells ($CD4^+$ T cells) are severely infected resulting in severe malnutrition, with anti-oxidants as taught by Khaled in order to bolster the immune competence of the patient and reduce the toxicity of the antiviral and/or antibacterial agent.

19. Claims 50, 51, 56, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillam (WO 01/89518 A1, Nov. 29, 2001) in view of Crawford (U.S. Patent No. 6,709,835, Filed Sept. 3, 1996) and Ajami (U.S. Patent No. 6,284,219, Filed June 30, 1998) as applied to claims 45 and 55 above, and further in view of Crum (WO 99/64022 A1, Dec. 16, 1999).

Gillam in view of Crawford and Ajami teaches a method for measuring effectiveness of therapy with anti-oxidant in a subject receiving treatment with an anti-oxidant as discussed above. However, Gillam in view of Crawford and Ajami fails to teach a method, wherein the anti-oxidant is IMMUNE FORMULATION 100™. For the purpose of examination, the IMMUNE FORMULATION 100™ has been interpreted in light of the current specification as defined on pp52-53.

Crum teaches a nutritional composition containing selenium (0.01-50g), colostrums (0.01-100g) and whey (0.01-100g) for enhancement of immune system and glutathione levels (p13, lines 17-25 and p31). Crum teaches that dietary supplement of selenium has been shown to provide a protective effect in cells against peroxidase (p13, lines 2-5).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Gillam in view of Crawford and Ajami with a nutritional composition of Crum containing selenium (0.01-50g), colostrums (0.01-100g) and whey (0.01-100g) in order to enhance of immune system and glutathione levels in an individual.

With respect to claims 51 and 56, Crum teaches a composition containing selenium (0.01-50g), colostrums (0.01-100g) and whey (0.01-100g) for enhancement of immune system and glutathione levels (p13, lines 17-25 and p31), wherein whey product contains substantially undenatured proteins (80%, p21, lines 4-11).

20. Claims 52 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillam (WO 01/89518 A1, Nov. 29, 2001) in view of Crawford (U.S. Patent No. 6,709,835, Filed Sept. 3, 1996) and Ajami (U.S. Patent No. 6,284,219, Filed June 30, 1998) as applied to claims 45 and 55 above, and further in view of Yegorova (U.S. PG Pub. No. US 2002/0176900 A1, Filed Nov. 22, 2000).

Gillam in view of Crawford and Ajami teaches a method for measuring effectiveness of therapy with anti-oxidant in a subject receiving treatment with an anti-

oxidant as discussed above. However, Gillam in view of Crawford and Ajami fails to teach a method, wherein the anti-oxidant comprises a formulation comprising a catalytic quantity of selenium source together with a mixture of glutamic acid, cysteine or cysteine precursor, and glycine, wherein the glutamic acid:cysteine or cysteine precursor:glycine ratio is 1:0.5:1. For the purpose of examination, the catalytic quantity of selenium source is interpreted in light of the current specification. The catalytic quantity of selenium precursor is defined by the current specification on p55, paragraph [0169] as an amount necessary to produce either in one dosage unit or in multiple dosage units sufficient elemental selenium to promote the production and activation of glutathione.

Yegorova teaches a composition comprising a catalytic quantity of selenium, cysteine, glutamic acid and glycine (p3, paragraphs [0015] and [0016]). Cysteine, glutamic acid and glycine form glutathione, an anti-oxidant important in many enzyme systems (p6, paragraph [0053], lines 1-9). Anti-oxidants made from glutathione and selenium protects cells against oxidative stress (p6, paragraph [0053], lines 9-12). Yegorova discloses the claimed composition except for glutamic acid, cysteine or cysteine precursor, and glycine having a ratio of 1:0.5:1, respectively. It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimal ratio of glutamic acid, cysteine or cysteine precursor, and glycine, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Gillam in view of Crawford and Ajami with a composition of Yegorova comprising a catalytic quantity of selenium and three amino acids, cysteine, glutamic acid and glycine, which comprise a glutathione, in order to enhance glutathione levels in an individual to protect cells against oxidative stress.

New Grounds of Rejection

21. Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillam (WO 01/89518 A1, Nov. 29, 2001) in view of Crawford (U.S. Patent No. 6,709,835, Filed Sept. 3, 1996), Ajami (U.S. Patent No. 6,284,219, Filed June 30, 1998), and Yegorova (U.S. PG Pub. No. US 2002/0176900 A1, Filed Nov. 22, 2000) as applied to claims 52 and 57 above, and further in view of Crum (WO 99/64022 A1, Dec. 16, 1999) and in light of Gu (U.S. PG Pub. No. US 2001/0050150 A1, Dec. 13, 2001).

Gillam in view of Crawford, Ajami, and Yegorova teaches a method for measuring effectiveness of therapy with anti-oxidant in a subject receiving treatment with an anti-oxidant as discussed above. However, Gillam in view of Crawford, Ajami, and Yegorova fails to teach a method, wherein the anti-oxidant comprises a formulation consisting of a glutathione precursor, which is IMMUNE FORMULATION 200™. For the purpose of examination, the IMMUNE FORMULATION 200™ has been interpreted in light of the current specification as defined on p54.

Crum teaches a nutritional composition containing selenium (0.01-50g), colostrums (0.01-100g) and whey (0.01-100g) for enhancement of immune system and

glutathione levels (p13, lines 17-25 and p31). Crum teaches that dietary supplement of selenium has been shown to provide a protective effect in cells against peroxidase (p13, lines 2-5). However, Crum fails to specifically teach that whey protein contains glutamic acid, cysteine and glycine. Gu teaches that whey protein includes contains glutamic acid, cysteine and glycine (p2, Table II). Therefore, one of ordinary skill in the art would recognize that the whey protein of Crum would inherently include glutamic acid, cysteine and glycine.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Gillam in view of Crawford Ajami, and Yegorova with a nutritional composition of Crum containing selenium (0.01-50g), colostrums (0.01-100g) and whey (0.01-100g), which includes include glutamic acid, cysteine and glycine, in order to enhance of immune system and glutathione levels in an individual.

Response to Arguments

22. Applicant's arguments filed on July 17, 2006 have been fully considered but they are not persuasive in view of previously stated rejections in the Office Action dated January 9, 2006.

23. Rejection under 35 U.S.C. 103(a) as being unpatentable over Gillam in view of Crawford and Ajami

Applicant argues that references cited by the Examiner in combination do not teach a method determining the effectiveness of an anti-oxidant treatment according to

claim 45 and 55 and the need for treatment according to claim 55. Applicant further argues that Gillam fails to teach measuring the amount of pyroglutamic acid (PGA). This argument is not found persuasive as Ajami teaches a method of measuring the amount of PGA, which is inversely proportional to the level of glutathione.

In addition Applicant argues that neither Crawford nor Ajami teach or suggest that administering an antioxidant has an effect on the levels of glutathione, lipid peroxides and PGA, which can be used to determine the effectiveness and/or need for therapy with anti-oxidant. This argument is not found persuasive as both Gillam and Ajami teach that the measurement of cytoprotective capacity and resistance to oxidative stress is reflected in the glutathione cycle as discussed above. Gillam further teaches that levels of glutathione and lipid peroxides can be used as oxidative stress. Since Ajami teaches that the amount of PGA is inversely proportional to the level of glutathione, it would be obvious to one of ordinary skill in the art at the time of the invention to measure the levels of PGA as an oxidative stress indicator in addition to glutathione and lipid peroxides. It has been long held that it is obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose. In re Kerhoven, 626, F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). As Crawford teaches that intervention with anti-oxidant nutrient supplements may have therapeutic benefit in humans, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide antioxidant therapy to those individuals with deficient anti-oxidants as taught by Crawford, where the oxidative stress in individuals is measured by the levels of glutathione, lipid peroxides and PGA as taught by Gillam and Ajami, in order to

identify individuals in need of therapy and to determine the effectiveness of the anti-oxidant therapy with a reasonable expectation of success as Gillam and Ajami teaches that levels of glutathione, lipid peroxides, and PGA are indicators of oxidative stress. Therefore, all the limitations of claims 45 and 55 as currently recited read upon the combined teachings of Gillam, Crawford, and Ajami.

24. Rejection under 35 U.S.C. 103(a) as being unpatentable over Gillam in view of Crawford and Ajami and Khaled

Applicant's argument that there is no suggestion in Khaled or in the combination of Gillam in view of Crawford and Ajami and Khaled that the nutritional supplement would have any effect on the levels and or amount of lipid peroxide, PGA and or blood plasma glutathione is not found persuasive in light of the reasons stated above paragraph #.

25. Rejection under 35 U.S.C. 103(a) as being unpatentable over Gillam in view of Crawford and Ajami and Crum

Applicant's argument that there is no suggestion in the combination of Gillam in view of Crawford and Ajami and Crum that the nutritional supplement would have any effect on the levels and or amount of lipid peroxide, PGA and or blood plasma glutathione is not found persuasive in light of the reasons stated above paragraph #.

26. Rejection under 35 U.S.C. 103(a) as being unpatentable over Gillam in view of Crawford and Ajami and Yegorova

Applicant's argument that there is no suggestion in the combination of Gillam in view of Crawford and Ajami and Yegorova that the nutritional supplement would have any effect

on the levels and or amount of lipid peroxide, PGA and or blood plasma glutathione is not found persuasive in light of the reasons stated above paragraph #.

27. Since prior art fulfills all the limitations currently recited in the claims, the invention as currently recited would read upon the prior art.

Conclusion

28. No claim is allowed.

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Unsu Jung, Ph.D.
Patent Examiner
Art Unit 1641

LONG V. LE 08/07/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600